### **COPY FOR IB**



# ENT COOPERATION TREATY



REC'D 13 JAN 2004

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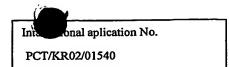
# **PCT**

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Artcle 36 and Rule 70)

	(202 12300000					
Applicant's or agent's file reference y01kp-121	FOR FURTHER ACTION SeeNotificationofTransmittalofInter Examination Report (Form PCT/IPE					
International application No. PCT/KR02/01540	International filing date(day/month/year) 13 AUGUST 2002 (13.08.2002)		Priority date (day/month/y 20 DECEMBER 2001 (2			
International Patent Classification (IPC)  IPC7 C07D 319/06	or national classification and IP	c				
Applicant CHOONGWAE PHARMA CORPORA	TION et al					
<ol> <li>This international preliminary ex and is transmitted to the applicant</li> <li>This REPORT consists of a total</li> <li>This report is also accompany</li> </ol>	t according to Article 36.  of sheets, incluanted by ANNEXES, i.e., sheets	ding this cover she	eet. 1, claims and/or drawings	which have been		
amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).  These annexes consist of a total ofsheets.						
3. This report contains indications relating to the following items:  I X Basis of the report  II Priority  III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability  IV Lack of unity of invention  V X Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement  VI Certain documents cited  VII Certain defects in the international application  VIII Certain observations on the international application						
Date of submission of the demand  18 JULY 2003 (18.07.2003)		Date of completion of this report  30 DECEMBER 2003 (30.12.2003)				
Name and mailing address of the IPEA Korean Intellectual Proper 920 Dunsan-dong, Seo-gu, Republic of Korea	ty Office Daejeon 302-701,	horized officer WON, Ho Joon				
Facsimile No. 82-42-472-7140	Tele	ephone No. 82-42	2-481-5605			





I.	Basis	s of the report						
1.	With	regard to the elements of the international application:*	-					
	X	X the international application as originally filed						
		the description:						
		pages	, as originally filed , filed with the demand					
		pages, filed with the letter of	, and the man delimine					
		the claims:						
	ш	nages	, as originally filed					
		pages, as amended (together with ar	y statment) under Article 19 , filed with the demand					
		pages, filed with the letter of						
		the drawings:						
		pages	, as originally filed					
	•	J. 10. 1	, filed with the demand					
		the sequence listing part of the description:						
	<b></b>	pages	, as originally filed					
		pages	, filed with the demand					
		pages, nied with the letter of						
2.	the international application was filed, unless otherwise indicated under this item.  These elements were available or furnished to this Authority in the following language English which is  the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).  The language of publication of the international application (under Rule 48.3(b)).  the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).							
3	3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:							
	님	contained in the international application in written form.						
	닖	filed together with the international application in computer readable form.  furnished subsequently to this Authority in written form.						
	닐							
	닏	furnished subsequently to this Authority in computer readable form  The statement that the subsequently furnished written sequence listing does not go b	evond the disc losure in the					
		international applicationas as filed has been furinshed.	270110 010 0100 100010 111 010					
		The statement that the information recorded in computer readable form is identical to the been furnished.	written sequence listing has					
4.		The amendments have resulted in the cancellation of:						
1		the description, pages						
		the claims, Nos.						
		the drawings, sheet						
5.		This report has been established as if (some of) the amendments had not been made, sinc go beyond the disclosure as filed, as indicated in the Supplemental Box(Rule 70.2(c)).**	ce they have been considered to					
*	in th	lacement sheets which have been furnished to the receiving Office in response to an invitation i his opinion as "originally filed." and are not annexed to this report since they do not contai 170.17).	under Article 14 are referred to in amendments (Rules 70.16					
	* Any	$\sigma$ replacement sheet containing such amendments must be referred $$ to under item $$ $$ $$ $$ $$ $$ and annexed	to this report.					



V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability
citations and explanations supporting such statement

1.	Statement			
	Novelty (N)	Claims	1 - 8	YES
		Claims		NO
	Inventive step (IS)	Claims	1 - 8	YES
		Claims		No
	Industrial applicability (IA)	Claims	1 - 8	YES
		Claims		NO

2. Citations and explanations (Rule 70.7)

The following documents are referred to:

D1: JP-A-06-107562 D2: US-A-5155251

#### 1. Novelty

D1 and D2 describe preparation methods of 2-[6-(substituted alkyl)-1,3-dioxane-4-yl] acetic derivative of Formula I, which is the final product of the present invention. However, the starting materials of the preparation methods in D1 and D2 are different from that of the present invention, which is an epoxide compound of Formula III. In addition, none of D1 and D2 teach  $\beta$ -hydroxyepoxycarboxyilic acid derivative of Formula II, which is the essential intermediate compound of the present invention.

Therefore, the subject matter of claims 1 to 8 seems to be novel (PCT Article 33(2)).

#### 2. Inventive Step

For the analysis of the inventive step, D1 is considered the closest prior art. D2 describes a method of the synthesis of 2-[6-(substituted alkyl)-1,3-dioxane-4-yl] acetic acid derivative, starting with 3-hydroxy-4-bromo ester, while the present invention, starting with an epoxide compound of Formula III and preparing  $\beta$ -hydroxyepoxycarboxyilic acid of Formula II through reaction steps a, b, c and D, and then, producing the final product of 2-[6-(substituted alkyl)-1,3-dioxane-4-yl] acetic derivative of Formula 1 by reacting said compound of Formula II through reaction steps e, f and g.

(Continued on Supplemental Sheet.)

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of:

Box V

As stated above, the final product of the present invention is the same as that of the invention of D1. However, the starting reaction material of the present invention is different from that of the invention of D1, and consequently the reaction mechanisms of both inventions are also different from each other. Accordingly, the difference in the constitution of the present invention is considered to be nonobvious to a person skilled in the art.

Such a difference in preparation method results in another difference: in D1, the reaction temperature is very low,  $-80\,^{\circ}$ C, while in the present invention, the reaction temperature ranges  $-20\,^{\circ}$ C to  $-30\,^{\circ}$ C, higher than the reaction temperature in D1. Accordingly, the present invention has an effect that it does not need any special reaction device and consequently it is an easy method for mass production.

Therefore, the subject matter of claims 1 to 8 does involve an inventive step in the sense of PCT Article 33(3).

3. Industrial Applicability

Claims 1 to 8 meet the criteria set out in PCT Article 33(4).